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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,464	04/29/2002	Peter L. Oren	29342/36230A	6930

4743 7590 04/06/2006

MARSHALL, GERSTEIN & BORUN LLP  
233 S. WACKER DRIVE, SUITE 6300  
SEARS TOWER  
CHICAGO, IL 60606

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/031,464

Applicant(s)

OREN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-16, 18-25 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-16, 18-25 and 28-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of response, declaration and terminal disclaimer all dated 12-27-05 is acknowledged.

Claims 1-4, 6-16, 18-25 and 28-36 are pending in the instant application.

#### ***Response to Arguments***

Applicants' arguments presented 12-27-05 regarding the following prior art rejection of record have been persuasive and hence the rejection has been withdrawn:

1. Claims 1-4, 6-16, 18-25 and 28-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03675 (Daung) in view of WO 96/38131 (Butler) and US 4,721,709 to Seth et al (Seth).

In response to the terminal disclaimer filed on 12-27-05, the following rejection has been withdrawn:

2. Claims 1-4, 6-16, 18-25 and 28-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U. S. Patent No. 6,821,975.

#### **The following is a new rejection:**

1. Claims 1-4, 6-16, 18-25 and 28-37 are directed to an invention not patentably distinct from claims 1-11 of commonly assigned US 6,821,975. Specifically, instant claimed composition containing a free drug, beta-carboline together with excipients and the method of treating sexual dysfunction using the composition comprising particulate form of the drug, is also claimed in the above patent applications. The patented claims

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of '975 recite compositions comprising the same free drug of instant compound, including particle sizes and broadly recite carriers or excipients, as in instant claims. While the patent fails to list the specific diluents and other excipients of the instant claims, choosing appropriate solvents, diluents, and other art recognized pharmaceutical excipients with an expectation to prepare a desired dosage form would have been obvious for one of an ordinary skill in the art.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,943,166, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

2. Claims 1-4, 6-16, 18-25 and 28-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,943,166 ('166) in view of US 6,821,975 ('975).

'166 claims a method of treating sexual dysfunction in a patient by administering a unit dose of a composition containing a compound, which is the same as the beta-carboline claimed in the instant invention. '166 claims unit dose in the form of a tablet, capsule, gel cap etc. '166 does not claim a pharmaceutical composition, free drug comprising particles, and the excipients of the instant claims.

'975 claim a composition and method similar to that of the instant claims. In particular, the compound claimed in '975 is the same as that of the free drug comprising particles, claimed in the instant invention. '975 broadly teach excipients such as diluents, carrier and diluents. Thus, the method claimed by '166 is the same as that of instant claims. All three sets of the claims employ the same compound as the active agent. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the compound of '166 to prepare a pharmaceutical composition in the form of tablets or capsules (such as those claimed in the instant), wherein the composition employs the active compound as it is or as a free drug comprising particles of the claimed sizes. While the instant claims recite specific excipients, '975 broadly suggests employing excipients and accordingly employing suitable excipients, diluents or carriers so as to prepare tablets or capsule that are effective in treating sexual dysfunction would have been within the scope of a skilled artisan. However, choosing appropriate solvents, diluents, and other art recognized

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pharmaceutical excipients with an expectation to prepare a desired dosage form would have been obvious for one of an ordinary skill in the art.

3. Claims 1-4, 6-16, 18-25 and 28-37 are directed to an invention not patentably distinct from claims 1-12 of commonly assigned US 6,943,166 in view of US 6,821,975. Specifically, instant claims composition containing a free drug, beta-carboline, together with excipients and the method of treating sexual dysfunction using the claimed composition comprising particulate form of the drug. US patent '166 claims a method of treating the same condition as that of the instant, employing the same compound. The patented claims of '975 recite free form drug, particle sizes and broadly recite carriers or excipients, similar to the instant claims. While the patent fails to list the specific diluents and other excipients of the instant claims, choosing an appropriate solvents, diluents, and other art recognized pharmaceutical excipients with an expectation to prepare a desired dosage form would have been obvious for one of an ordinary skill in the art.

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,821,975, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were

commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

***Claim Rejections - 35 USC § 103***

Claims 1-4, 6-16, 18-25 and 28-37 are rejected under 35 U.S.C. 103(a) as being obvious over Us 6,943,166.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

'166 teaches pharmaceutical compositions comprising beta-carboline compound having the same formula as that of the instant claims and for treating the same method i.e., erectile dysfunction. '166 teaches 1-20 mg of active compound (also claimed in the instant) in an oral dosage form such as tablets or capsules (col. 3, lines 1-5 and 55-59), wherein the drug is present as a "free drug" i.e., solid particles of drug not intimately embedded in a polymeric co-precipitate (col. 4, lines 1-3, lines 61-64). '166 further teaches excipients and methods of preparing the dosage forms such as those claimed as well as described in the instant application (examples in col. 10-11). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a composition comprising the claimed compound as a free drug, having particle size of 90% particles being less than 40 microns, and preparing tablets or capsule with the excipients because '166 teaches that the dosage forms with a free drug is preferred and '166 also teaches a method of treating the same conditions as claimed. Accordingly, a skilled artisan would have been able to provide an effective treatment for sexual dysfunction with a composition containing free drug particles.

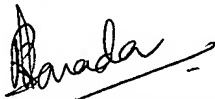


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
March 31, 2006